

ROUTING AND RECORD SHEET

SUBJECT: (Optional)

FROM

EXTENSION

NO.

STAT

ID4027 Hqs

DATE

19 March 1981

TO: (Officer designation, room number, and building)

DATE

OFFICER'S INITIALS

COMMENTS (Number each comment to show from whom to whom. Draw a line across column after each comment.)

RECEIVED

FORWARDED

1. Director of Medical Services 23 MAR 1981 24 MAR 1981 Rm

2. Eo/DOA 25 MAR 1981 25 MAR 1981 mfe

3. Registry

4. Deputy Director for Administration

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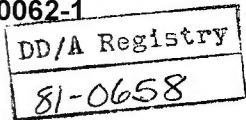
15.

Called to

attention
3/25/81 - mfe

③ file

DOA REGISTER
FILE: O+M-1



19 March 1981

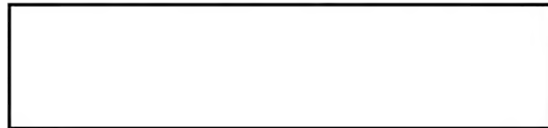
MEMORANDUM FOR: Deputy Director for Administration

VIA: Robert A. Ingram, M.D.
Director of Medical Services

STAT FROM:
Chairman, Agency Task Force in Support of
Liaison With the President's Commission for
the Study of Ethical Problems in Medicine and
Biomedical and Behavioral Research

STAT SUBJECT: Revision of

STAT Attached is a revision of with special reference to
restrictions on human experimentation, the definition of an
Agency Human Subject Research Panel and the operation of
Institutional Review Boards within the Agency context. While
a number of components in the Directorate may potentially be
concerned with such research, you may wish to bring this to
the particular attention of the Director of Logistics, who
monitors contracts let by the Agency to external groups.



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STAT Attachment:
Revision of

HQ. INSTRUCTION SHEET 1377

REMOVE			INSERT			EXPLANATION
REG. NOS.	PAGE NOS.	DATE	REG. NOS.	PAGE NOS.	DATE	
	2 3&4 7&8	11/21/79 9/15/78 9/15/78		2 3&4 4.1- 4.2 6.1 6.2 7-8	1/16/81 1/16/81 9/15/78 1/16/81 9/15/78 9/15/78	<div></div> is revised to define the Institutional Review Board and research on human subjects. Paragraph c(1)(k) is expanded to establish and define the functions of the Human Subject Research Panel. Paragraph c(1)(k) is also revised to reflect the redesignation of the Department of Health, Education and Welfare as the Department of Health and Human Services.
Arrows in the page margin show the locations of the changes described above.						

DISTRIBUTION: AB

MANAGEMENT

1. RESTRICTIONS ON INTELLIGENCE ACTIVITIES

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SYNOPSIS. This regulation implements the provisions of Executive Order 12036 that impose various restrictions on the intelligence activities of the Agency, particularly with regard to activities involving United States persons. The regulation also includes Agency policies regarding, among other things, the conduct of security investigations, relations between the Agency and other governmental entities, and relationships between the Agency and members of the U.S. news media, U.S. clergy, the U.S. academic community, and employees of the Congress.

a. GENERAL

- (1) The intelligence activities of the United States, including the activities of the Agency and the Office of the Director, are restricted by various provisions of law and, in particular, Executive Order 12036 (43 Fed. Reg. 3674, 26 January 1978), particularly Section 2. Provisions of the Executive Order which are quoted in this regulation are indicated by italics. Nothing in these portions of the Executive Order or this regulation is intended to authorize any activity not otherwise authorized or to provide exemption from any more restrictive statute, Presidential directive, Executive order, or regulation. Unless otherwise specified, the provisions of this regulation apply to activities of both the Agency and the Office of the Director whether inside or outside the United States. References to law are to the Constitution and applicable laws of the United States. This regulation will not be amended without the approval of the Director or the Deputy Director of Central Intelligence.
- (2) No activity or action shall be authorized which would intentionally, or reasonably would be expected to, abridge the Constitutional or legal rights of U.S. persons, whether in the United States or abroad.
- (3) To ensure that all activities are in compliance with the law, Deputy Directors and Heads of Independent Offices shall consult with the Office of General Counsel on all activities whose legality is not clearly established. The General Counsel shall have access to all information necessary to perform the duties of that office (see [redacted]).
- (4) The Inspector General is authorized to review all activities and shall have access to all information necessary to perform the duties of that office (see [redacted]).
- (5) Any activities or proposed activities that may raise questions of compliance with law, Executive order, or regulation, or that may otherwise appear improper, will be brought directly to the attention of the Director.
- (6) Any employee who has knowledge of past, current, or proposed CIA activities that might be construed to be illegal, improper, questionable, or not authorized by applicable law, Presidential directive, Executive order, or regulation, or who believes that instructions received in any way appear to be illegal, improper, or questionable, shall inform the Director or Inspector General immediately.
- (7) Any employee who, in the course of official duty, becomes aware of any information, allegation, or complaint of possible violations of Federal criminal law by any person, including a person employed by, assigned to, or acting for the Agency, is required to report immediately such information, allegation, or complaint to the General Counsel. The Office of General Counsel shall consult with the Office of Security and the Office of the Inspector General when necessary in conducting a preliminary inquiry to determine whether a basis for referral exists and shall obtain from concerned Agency components an evaluation of the impact, if any, of a prosecution of such a violation on the national security or foreign relations of the United States, including intelligence operations which

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may be jeopardized or intelligence sources and methods which may be compromised. Pursuant to 28 U.S.C. 535 and Section 1-706 of Executive Order 12036, evidence of possible violations of Federal criminal law shall be reported expeditiously to the Attorney General by the General Counsel in accordance with procedures and guidelines adopted by the Attorney General. Cases involving breaches of security shall be reported to the Director of Security, who shall inform the General Counsel of serious or continuing breaches. The General Counsel shall, in compliance with Section 1-707 of Executive Order 12036, recommend to the Attorney General that such cases be referred to the FBI for further investigation. (Required procedures and guidelines will be included as Annex F.)

- (8) The provisions of any previously published regulatory issuance inconsistent with the provisions of this regulation are superseded.

b. DEFINITIONS. For the purpose of this regulation, and except as may be provided in the annexes to this regulation, the following terms shall have these meanings.

- (1) *"Communications security" means protective measures taken to deny unauthorized persons information derived from telecommunications of the United States Government related to national security and to ensure the authenticity of such telecommunications.*
- (2) *"Counterintelligence" means information gathered and activities conducted to protect against espionage and other clandestine intelligence activities, sabotage, international terrorist activities or assassinations conducted for or on behalf of foreign powers, organizations or persons, but not including personnel, physical, document, or communications security programs.*
- (3) *"Electronic Surveillance" means acquisition of a nonpublic communication by electronic means without the consent of a person who is a party to an electronic communication or, in the case of a nonelectronic communication, without the consent of a person who is visibly present at the place of communication, but not including the use of radio direction finding equipment solely to determine the location of a transmitter. The monitoring of a telephone conversation with the consent of one party does not constitute electronic surveillance under this definition. This is consistent with Title III of the Omnibus Crime Control and Safe Streets Act of 1968. Also, the recording of an ordinary oral conversation by someone who can be seen by both parties to it, and is in reasonably close proximity to the parties and therefore can reasonably be expected to overhear it, does not constitute electronic surveillance.*
- (4) *"Employee" means persons employed by, assigned to, or acting for the Agency and the Office of the Director, except as otherwise defined in the annexes to this regulation.*
- (5) *"Foreign Intelligence" means information relating to the capabilities, intentions and activities of foreign powers, organizations or persons, but not including counterintelligence except for information on international terrorist activities.*
- (6) *"Institutional Review Board" means a panel created in accordance with the requirements of 45 CFR 46 by an institution (external contractor or Agency component) conducting research on human subjects, responsible for determining whether human research subjects will be placed at risk and, if risk is involved, whether (a) the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks, (b) the rights and welfare of any such subject will be adequately protected, and (c) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of 45 CFR 46.*
- (7) *"Intelligence" means foreign intelligence and counterintelligence.*

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- (8) *"Intelligence Community" and "agency" or "agencies within the Intelligence Community" refer to the following organizations:*
 - (a) *The Central Intelligence Agency (CIA);*
 - (b) *The National Security Agency (NSA);*
 - (c) *The Defense Intelligence Agency;*
 - (d) *The Offices within the Department of Defense for the collection of specialized national foreign intelligence through reconnaissance programs;*
 - (e) *The Bureau of Intelligence and Research of the Department of State;*
 - (f) *The intelligence elements of the military services, the Federal Bureau of Investigation (FBI), the Department of the Treasury, the Department of Energy, and the Drug Enforcement Administration (DEA); and*
 - (g) *The staff elements of the Office of the Director of Central Intelligence (see [redacted])*
- (9) *"International terrorist activities" means any activity or activities which:*
 - (a) *involves killing, causing serious bodily harm, kidnapping, or violent destruction of property, or an attempt or credible threat to commit such acts; and*
 - (b) *appears intended to endanger a protectee of the Secret Service or the Department of State or to further political, social or economic goals by intimidating or coercing a civilian population or any segment thereof, influencing the policy of a government or international organization by intimidation or coercion, or obtaining widespread publicity for a group or its cause; and*
 - (c) *transcends national boundaries in terms of the means by which it is accomplished, the civilian population, government, or international organization it appears intended to coerce or intimidate, or the locale in which its perpetrators operate or seek asylum.*
- (10) *"Physical surveillance" means an unconsented, systematic and deliberate observation of a person by any means on a continuing basis, or unconsented acquisition of a nonpublic communication by a person not a party thereto or visibly present thereat through any means not involving electronic surveillance. This definition does not include overhead reconnaissance not directed at specific United States persons. The definition of physical surveillance refers primarily to systematic observation of an individual designed to determine all of his or her regular daily activities. The unconsented acquisition of a nonpublic communication by a person not a party thereto or visibly present thereat refers primarily to a situation where a person hides in a room to overhear what persons in the room are saying.*
- (11) *"Research on human subjects" means a formal investigation, designed to develop or contribute to generalizable knowledge, the subjects of which are persons about whom a scientist conducting research obtains data through intervention or interaction with the person or identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulation of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the research scientist and the subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable to fall within this definition. Data collection and analysis conducted within the limits of the normal course of approved administrative, analytical, or operational activities does not constitute research under this definition.*
- (12) *"Special activities" means activities conducted abroad in support of national foreign policy objectives which are designed to further official United States programs and*

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policies abroad and which are planned and executed so that the role of the United States Government is not apparent or acknowledged publicly, and functions in support of such activities, but not including diplomatic activity or the collection and production of intelligence or related support functions.

- (13) *"United States," when used to describe a place, includes the territories of the United States.*
- (14) *"United States person" means:*
 - (a) *A citizen of the United States;*
 - (b) *An alien lawfully admitted for permanent residence;*
 - (c) *An unincorporated association organized in the United States or substantially composed of United States citizens or aliens lawfully admitted for permanent residence; or*
 - (d) *A corporation incorporated in the United States.*

c. POLICY

(1) RESTRICTIONS ON COLLECTION

(a) General Provisions

- (1) *The activities described in paragraphs (b) through (s) below shall be undertaken only as permitted by this regulation and, where required, by procedures established by the Director and approved by the Attorney General. Those procedures shall protect constitutional rights and privacy, ensure that information is gathered by the least intrusive means possible, and limit use of such information to lawful governmental purposes.*
- (2) *Activities described in paragraphs (b) through (e) for which a warrant would be required if undertaken for law enforcement rather than intelligence purposes shall not be undertaken against a United States person without a judicial warrant, unless the President has authorized the type of activity involved and the Attorney General has both approved the particular activity and determined that there is probable cause to believe that the United States person is an agent of a foreign power.*

- (b) *Electronic Surveillance. The CIA may not engage in any electronic surveillance within the United States. No agency within the Intelligence Community shall engage in any electronic surveillance directed against a United States person abroad or designed to intercept a communication sent from, or intended for receipt within, the United States, except as permitted by the procedures established pursuant to paragraph c(1)(a). Training of personnel by agencies in the Intelligence Community in the use of electronic communications equipment, testing by such agencies of such equipment, and the use of measures to determine the existence and capability of electronic surveillance equipment being used unlawfully shall not be prohibited and shall also be governed by such procedures. Such activities shall be limited in scope and duration to those necessary to carry out the training, testing or countermeasures purpose. No information derived from communications intercepted in the course of such training, testing or use of countermeasures may be retained or used for any other purpose. (See classified Annex B for required procedures concerning electronic surveillance and training and testing in this area, which shall remain in effect until such time as final procedures for electronic surveillance, testing, and audio countermeasures activities are developed under paragraph c(1)(a).) CIA may request other agencies with authority to do so to conduct electronic surveillance within the U.S. for legitimate foreign intelligence or counterintelligence purposes, and CIA may aid such agencies in the conduct of electronic surveillance within the U.S. for foreign intelligence*

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or counterintelligence purposes, through the provision of technical assistance and expert personnel, provided OGC is consulted prior to requesting such surveillance or furnishing such assistance or personnel.

- (c) **Television Cameras and Other Monitoring.** *No agency within the Intelligence Community shall use any electronic or mechanical device surreptitiously and continuously to monitor any person within the United States, or any United States person abroad, except as permitted by the procedures established pursuant to paragraph c(1)(a). (Required procedures will be included as Annex G at such time as they have been established and approved. In the interim, OGC must be consulted prior to initiating any such activity.)*
- (d) **Unconsented Physical Searches.** *No agency within the Intelligence Community except the FBI may conduct any unconsented physical searches within the United States. All such searches conducted by the FBI, as well as all such searches conducted by any agency within the Intelligence Community outside the United States and directed against United States persons, shall be undertaken only as permitted by procedures established pursuant to paragraph c(1)(a). (See classified Annex C for required procedures which shall remain in effect until such time as revised under paragraph c(1)(a). In the interim, OGC must be consulted prior to initiating any such activity.)*
- (e) **Mail Surveillance.** *No agency within the Intelligence Community shall open mail or examine envelopes in United States postal channels, except in accordance with applicable statutes and regulations. No agency within the Intelligence Community shall open mail of a United States person abroad except as permitted by procedures established pursuant to paragraph c(1)(a). The opening of mail of a U.S. person abroad constitutes an unconsented physical search directed at that person and is limited as in (d) above. To the extent CIA may need mail cover information from within U.S. postal channels in furtherance of its legitimate activities, it shall make*

(Continued on page 5.)

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(k) **Restrictions on Experimentation.** No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines.

(1) The Director, through an Agency Human Subject Research Panel (HSRP), hereby established, shall evaluate all documentation and certification pertaining to human research sponsored by, contracted for, or conducted by the CIA (including initial and ongoing reviews conducted by Institutional Review Boards) prepared in compliance with Department of Health and Human Services guidelines, codified at 45 CFR 46. The HSRP shall be composed of such offices and employees of the CIA and such experts or consultants engaged for this purpose as the Director determines to be appropriate.

(2) On the basis of his evaluation of documentation submitted in accordance with the requirements of this regulation, the Director shall approve, require such modifications to submissions as to make them acceptable, or disapprove. With respect to approved documentation, the Director may determine the period during which approvals remain effective or otherwise condition or restrict his approval.

(3) The Agency HSRP shall disseminate procedural instructions and information necessary for the establishment and operation of Institutional Review Boards within the Agency as required by 45 CFR 46. The HSRP shall provide material to assist the components to comply with [redacted] and shall standardize information necessary for documentation and certification as required by 45 CFR 46 of institutions conducting research on human subjects.

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(l) Not used.

(m) **Restrictions on Contracting.** No agency within the Intelligence Community shall enter into a contract or arrangement for the provision of goods or services with private companies or institutions in the United States unless the agency sponsorship is known to the appropriate officials of the company or institution. In the case of any company or institution other than an academic institution, intelligence agency sponsorship may be concealed where it is determined, pursuant to procedures approved by the Attorney General, that such concealment is necessary to maintain essential cover or proprietary arrangements for authorized intelligence purposes. (Required procedures are included as Annex L.)

(n) **Restrictions on Personnel Assigned to Other Agencies.** An employee detailed to another agency within the federal government shall be responsible to the host agency and shall not report to the parent agency on the affairs of the host agency unless so directed by the host agency. The head of the host agency, and any successor, shall be informed of the employee's relationship with the parent agency. In accordance with [redacted] CIA personnel assigned to other Government agencies for cover purposes, and liaison officers, are not considered to be "detailed" to the other agency involved.

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(o) **Prohibition on Assassination.** No person employed by or acting on behalf of the United States Government shall engage in, or conspire to engage in, assassination.

(p) **Restrictions on Special Activities.** No component of the United States Government except an agency within the Intelligence Community may conduct any special activity. Only CIA (or the military services in wartime) may conduct special activities, except where the President determines, with the advice of the Special Coordination Committee of the National Security Council, that another

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agency is more likely to achieve a particular objective. Special activities must be approved in accordance with Section 1-302 of Executive Order 12036.

- (q) **Restrictions on Indirect Participation in Prohibited Activities.** No agency of the Intelligence Community shall request or otherwise encourage, directly or indirectly, any person, organization, or government agency to undertake activities forbidden by Executive Order 12036 or by applicable law.
- (r) **Restrictions on Assistance to Law Enforcement Authorities.** Agencies within the Intelligence Community other than the FBI shall not, except as expressly authorized by law:
 - (1) Provide services, equipment, personnel or facilities to the Law Enforcement Assistance Administration (or its successor agencies) or to state or local police organizations of the United States; or
 - (2) Participate in or fund any law enforcement activity within the United States.
- (s) **Permissible Assistance to Law Enforcement Authorities.** The restrictions in paragraph (r) shall not preclude:
 - (1) Cooperation with appropriate law enforcement agencies for the purpose of protecting the personnel and facilities of any agency within the Intelligence Community;
 - (2) Participation in law enforcement activities, in accordance with law and this regulation, to investigate or prevent clandestine intelligence activities by foreign powers, international narcotics production and trafficking, or international terrorist activities;
 - (3) Provision of specialized equipment, technical knowledge, or assistance of expert personnel for use by any department or agency or, when lives are endangered, to support local law enforcement agencies. Provision of assistance by expert personnel shall be governed by procedures approved by the Attorney General; (Required procedures will be included as Annex M at such time as they have been established and approved.)
- (4) The following relationships to support legitimate activities:
 - (a) LEAA assistance may be requested through the Office of Security for evaluative information on equipment and techniques with respect to terrorist problems.
 - (b) Contact may be maintained with and assistance sought from State and local police organizations in the course of normal background and security investigations, for the protection of Intelligence Community personnel and installations, and in connection with other permissible activities.
 - (c) Contact also may be maintained with police department bomb squads to observe their techniques in identifying, handling, and disarming terrorist bombs and to discuss technical aspects of countering explosive devices. The purpose will be to obtain information on bomb handling and not to train the local police departments.
 - (d) Attendance may be authorized, in accordance with paragraph c(1)(g) above, at explosive ordnance disposal conferences and similar briefings or seminars to keep abreast of new developments in terrorist techniques and countermeasures.
 - (e) It is appropriate to have individual relationships with State and local police organizations for cooperation in training employees in the United States preparatory to their assignment abroad. It should be clearly indicated that this is a training relationship, and no operational assistance will be given to police organizations in the course of training personnel.

- (2) **PERMISSIBLE DISSEMINATION AND STORAGE OF INFORMATION.** *Nothing in paragraphs c(1)(a) through (s) shall prohibit:*
- (a) *Dissemination to appropriate law enforcement agencies of information which indicates involvement in activities that may violate federal, state, local or foreign laws;*
 - (b) *Storage of information required by law to be retained;*
 - (c) *Dissemination of information covered by paragraphs c(1)(h)(1)-(10) to agencies within the Intelligence Community or entities of cooperating foreign governments;*
 - (d) *Lawful storage or dissemination of information solely for administrative purposes not related to intelligence or security; or*
 - (e) *Dissemination of foreign intelligence and foreign counterintelligence information directly to the interested Federal agency. Dissemination of such information beneficial to State and local law enforcement agencies or LEAA will be made only through the FBI.*

→ Any question as to whether information concerning United States persons conforms to that permitted to be collected by paragraph c(1)(h) above or E.O. 12036 shall be referred to the Office of General Counsel. Access to information on United States persons determined by the Office of General Counsel to be in violation of paragraph c(1)(h) or E.O. 12036, as well as access pending legal review, will be permitted only to the extent necessary to meet the requirements of the Freedom of Information Act, the Privacy Act, other law, court orders, or investigations by the Inspector General, the Department of

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